

REMARKS

Claims 1-4 and 6-21 are pending in this application. Claims 1-4 and 6 stand rejected. Claims 7-21 have been withdrawn from consideration as being drawn to the non-elected invention. None of the claims stand objected to. The Applicants herein amend Claims 1, 3, 4, and 6. Claims 1 and 6 were amended to correct obvious typographical errors. Support for Claims 3 and 4, as amended, can be found in the as-filed claims and specification. Accordingly, these amendments introduce no new matter.

In view of the following amendment and response, the Applicants believe the claims presented herein are allowable. Reconsideration is respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

The Examiner maintained the rejections of Claims 3 and 4 under 35 U.S.C. § 112, first paragraph. He states that Applicants have not furnished any additional arguments for the limitation of "functional equivalents" in these claims. In response to this rejection, the Applicants have amended Claims 3 and 4, so as to delete this limitation. None of the pending claims now recite "functional equivalents." The Applicants apologize to the Examiner for this oversight from their last response.

The Applicants respectfully submit that, in view of the forgoing remarks and the claims as amended, the Applicants have overcome the rejection of Claims 3 and 4 under 35 U.S.C. § 112, first paragraph. Accordingly, the Applicants respectfully request withdrawal of these rejections.

REJECTIONS UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 1-4 and 6 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. The Examiner contends that the

claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner alleges that the instant specification lacks adequate written description for an “agent” that modulates transcriptional activity of Smad proteins with a DNA element. He further contends that the Applicants do not appear to have reduced to practice a representative number of such “agents”. To support this argument, the Examiner relies upon two sources: (1) the Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. § 112, ¶ 1 “Written Description” Requirement, 66 Fed. Reg. 1099-1111 (Friday, January 5, 2001) (herein referred to as “the Written Description Guidelines”); and (2) *Regents of the University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997).

The Applicants respectfully traverse these rejections. Because the Applicants are not claiming the “agents” themselves, the law requires them to fulfill the written description requirement with respect to the claimed screening methods only. The Applicants comply with the written description requirement by disclosing a number of screens that can be used to identify the recited “agents,” in the Examples section of the instant specification (pages 28 through 33). While the Examiner opines on page 4 of the Office Action that the instant method claims require adequate written description of the “agents” employed in the methods, he cites no PTO rules or case law to support this assertion. Neither of the citations he relies on in the Office Action, the PTO’s Written Description Guidelines or *Eli Lilly*, state the presence of this requirement.

In fact, the discussion in the Written Description Guidelines that relates to the need for applicants to disclose a “representative number” of species concerns claims to a genus. The Applicants assert that this requirement pertains only to composition of matter claims. In

describing transcriptional screens that may be used to identify the recited “agents”, the Applicants have satisfied their burden under the written description requirement.

Furthermore, *Lilly* supports the Applicants’ position. The portion of the case upon which the Examiner relies concerns adequate description of genetic material. Specifically, the claims at issue in *Lilly* were drawn to mammalian coding sequences (cDNAs), not to screening methods. In *Lilly*, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

43 U.S.P.Q.2d at 1406.

The Applicants respectfully submit that the Examiner has inappropriately stretched both the Written Description Guidelines and the holding in *Lilly* beyond their intended bounds. In other words, the disclosure of these screens proves that the Applicants were in possession of the inventive screening methods as of the filing date. The law requires no more. Following the Examiner’s argument to its logical conclusion would make screening patents virtually impossible to obtain. This is certainly not the case. The inventive screening methods aim to identify desired agents amongst an extremely large pool of potential candidate agents.

The Applicants respectfully submit that, in view of the forgoing remarks, they have overcome the Examiner’s rejection of Claims 1-4, and 6 under 35 U.S.C. § 112, first paragraph. Accordingly, the Applicants respectfully request reconsideration and withdrawal of these rejections.

CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e)

Claims 1-3 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Laughon, *et al.* (U.S. Patent Number 6,046,165) (hereinafter referred to as “Laughon”).

According to the Examiner, Laughon discloses a method of screening comprising Smad proteins, a nucleic acid substrate of which is a double-stranded molecule. He further contends that Laughon discloses a sequence that comprises the sequence AG(C/A)CAGACA (Claim 3). In addition, the Examiner states that Laughon discloses a sequence that comprises the WXYCAGACZ motif, wherein the motif is comprised within that of SEQ ID NOs: 10 and 11.

The Applicants respectfully traverse these rejections. A single prior art reference anticipates a claimed invention only if it identically shows every element of the claimed invention. *In re Bond*, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990). Moreover, the law requires that an anticipating reference must also be enabled. *In re LeGrice*, 133 U.S.P.Q. 365, 376-77 (C.C.P.A. 1962). The Applicants submit that Laughon does not anticipate the claimed invention, both because it does not identically show every element of the claimed invention, and because it does not enable the instantly claimed screening methods.

The screening methods of Laughon differ from those of the Applicants' in at least two respects. First, whereas Laughon's claims are based upon the description of a protein (Smads) / DNA interaction (column 15, lines 17-24), the Applicants provide evidence that their recited oligonucleotide is functional in a more physiological cellular system. See, for example, pages 22-28 of the instant specification. Therefore, the Applicants submit that Laughon's disclosed screening methods are not enabling with respect to the instantly pending claims.

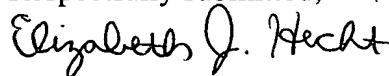
Second, Laughon's consensus sequence is GCCGnCGc (SEQ ID NO:9) (column 6, line 21), whereas the Applicants disclose a precise Smad binding element that is critical for gene transcription, AG(C/A)CAGACA. The Examiner points out that the Applicants' consensus is contained within Laughon's SEQ ID NOs: 10 and 11. However, this fact does

not change the analysis. The oligos used by Laughon are longer than those used by the Applicants, a fact which could certainly change the results of transcriptional screens used to identify "agents". In other words, Laughon does not disclose the exact oligonucleotide recited by the instant claims. In that Laughon does not identically show every element of the instantly pending method claims, it does not constitute an anticipating reference under *In re Bond*.

The Applicants respectfully submit that, in view of the forgoing remarks and the claims as amended, the Applicants have overcome the rejection of Claims 1-3 under 35 U.S.C. § 102(e). Accordingly, the Applicants respectfully request reconsideration and withdrawal of these rejections.

The Applicants reserve the right to prosecute, in one or more patent applications, the claims to non-elected inventions, the claims as originally filed, and any other claims supported by the specification. The Applicants thank the Examiner for the Office Action and believe this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration and allowance of the pending claims is earnestly solicited. If it would expedite the prosecution of this application, the Examiner is invited to confer with the Applicants' undersigned attorney.

Respectfully submitted,



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